REMARKS

COMMENTS CONCERING THE EXAMINER'S COMMENTS ON THE INTERVIEW SUMMARY, AS CONTAINED IN THE OFFICE ACTION OF AUGUST 6, 2009.

While the Examiner states, at page 8, paragraph number 5, that the "Interview Summary dated 4/28/09 does not state the claims will be allowable upon amending the claims to recite the above features" the Examiner has clearly withdrawn the previous rejections of the claims as unpatentable over the proposed combination of Blume et al (U.S. Patent No: 6,372,252) in view of Dansereau et al. (U.S. Patent 5,032,406), Troy et al. (U.S. Patent 3,627,583) and Ansel et al (pharmaceutical dosage forms) as this rejection does not appear in the Office Action of August 6, 2009.

Accordingly the Examiner's Action confirms that the amended claims are indeed patentable over the previous rejections.

However, in view of the fact that the Examiner has found a new reference, Wilber et al. (U.S. Patent 6,623,756) and upon the basis of Wilber et al. in combination with the aforementioned Blume et al., Dansereau et al., and Troy et al. a new ground of rejection has been made.

RECONSIDERATION OF THE PRIOR ART REJECTIONS

Reconsideration of the rejections set forth in the Office Action mailed August 6, 2009, are respectfully requested in view of the following comments.

Before responding in detail applicants wish to reiterate that the invention, as claimed, is clearly not set forth in the Office Action, nor does it appear to be appreciated by the Examiner.

Independent claim 37, upon which all other claims are dependent, recites "a tablet formed by compressing in a tableting press a free flowing granular composition

comprising an agglomerate of guaifensesin and a binder therefore". The binder "comprising from abut 1.0 to about 7% by weight polyvinylpyrrolidone, and from about 0.2 to about 4% by weight of solubilizer, or distintegrant, or solubilizer and disintegrant". "The tablet also comprises from about 0.1 to about 2 wt% of a lubricant". The "free flowing agglomerate exhibits a flow rate greater or equal to 6.5 grams per second as measured in a VanKel flowmeter and is direct compression tableted in a tableting press operating at no more than 2.5 tons". The "tablets exhibiting less than 1% friability, a hardness in the range of 10.3 to 17.0 kp, and is resistant to capping". In order to achieve the tablet it is required that the "composition comprising particles having a sieve analysis, based on the total weight of the components of the composition, wherein 0% by weight of the particles exhibit a particle size greater than 425 micrometers and greater than about 85% by weight of the particles exhibit a particle size greater than about 45 micrometers, and the composition comprises from about 85% by weight to about 97.5% by weight guaifenesin". By contrast the four references cited in the rejection do not contain a teaching of all the recited limitations of applicant's claims.

Under *KSR* the Examiner must act as a fact finder and locate, in the prior art references, all of the limitations specified by the claims.

In the instant case the Examiner has failed to locate references teaching all of the claimed limitations.

It is initially noted that the statement of the rejection rejects "claims 1-8 and 31-37 under 35 U.S.C. 103 (a)". However, only claims 2-4, 8, 33-34 and 37 are pending. Thus, applicants confirm their comments to the pending claims rejected.

It is clear that when reviewing the cited references, the Examiner is overstating the teachings of the references in a strained attempt to meet the limitations of the claims.

For example, with regard to Blume et al. (discussed on page 3 of the Office Action) the Examiner states "thus, the resulting material of Blume "reads on

agglomerated mixture because the processing of the material involves the same steps as described in the instant application". This is incorrect. In order to "read on" Blume, Blume would have to teach an agglomerated mixture not only containing guaifenesin but also the other recited components i.e. a binder from about 1.0 to about 7% by weight polyvinylpyrrolidone (which the Examiner concedes it does not) and from about 0.2 to about 4% by weight of solubilizer, or distintegrant, or solubilizer and disintegrant; and from about 0.1 to about 2 wt % of a lubricant. Furthermore, not only do the claims specify the chemical composition of the agglomerate but also the physical properties i.e. "0% by weight of the particles exhibit a particle size greater than 425 micrometers(equivalent to about a number 40 standard sieve or about a 35 mesh Tyler equivalent – see the client in Perry's Chemical Engineer's Handbook, Sixth Edition page 21-15 (a copy of which was attached to the amendment filed October 26, 2007).

What is important about these limitations on the nature of the agglomerate is that only these particular limitations can produce a tablet under relatively low pressure (not more than 2.5 tons) which exhibits less than 1% friability, a hardness in the range of 10.3 to 17.0 kp and is resistant to capping).

Having now compared the teachings of Blume with only independent claim 37, it can be seen that Blume clearly does not teach an agglomerate of guaifenesin and polyvinylpyrrolidone. Blume specifically teaches that his granulation far exceeds the maximum particle size permitted, i.e. Blume states his granulation has "not more than about 10% of the resulting granulation is retained on a 10 mesh screen"(about 2.0mm) – more than 400% larger than that permitted in the instant claim (see column 8, lines 22-23 of Blume et al.). While it is stated that the resulting formulation "may further be compressed on a tablet compressing machine using tooling to form tablets (column 8, lines 36-37) no disclosure of the pressure of the tableting press, nor of the resulting tablet

properties as far as hardness, capping and friability can be found within the four corners of the Blume et al. reference.

Faced with the serious deficiencies of the Blume et al. reference as a basic teaching reference for the claimed invention, the Examiner then attempts to cobble together the previously cited Dansereau et al. and Troy et al. references. Even these references do not establish a prima facie case of obviousness in the Examiner's mind because she now finds it necessary to cite the Wilber et al. Patent.

However, Wilber et al., like the other references discussed above, contains a disclosure which is not sufficient to teach the missing features of the previous combination of references.

For example, while it is apparent that the Examiner's citation to Wilber et al. is aimed at teaching an agglomerate of the claimed particle range, it appears that the Examiner clearly miscomprehends Wilber et al., and any attempt at reliance on Wilber et al., is clearly misplaced, insofar as the portion cited by the Examiner e.g., column 4, lines 44-48, is not directed to an agglomerate at all, and certainly not an agglomerate comprising guaifenesin and a binder, but rather is to the physical properties of the rheology modified polymer or co-polymer alone.

If the Examiner would have read beyond line 48, of column 4 it is clearly stated by Wilber et al., that "desirably, the particle or granular size of the one or more polymers or co-polymers can be classified as falling within size ranges as defined by U.S. standard mesh screens. For example, the particle size of the granulated rheology modifying polymers or copolymers is generally that which falls through 40 mesh but is retained on 200 mesh..." (compare these mesh sizes with the corresponding micrometer equivalents in the aforementioned Perry's Chemical Engineer's Handbook).

Although the Examiner needs to find an agglomerate of the particle size as claimed, all that Wilber et al. teach is the rheology modifying polymer or copolymer

having the described particle sizes identified at column 4 lines 48 to column 5 line 10. If the Examiner would have continued her reading through the potential active ingredients which can be incorporated with the rheology modified polymer or copolymer, beginning at column 5, line 53 through column 7, line 49, it will be seen that Wilber et al. only suggest that "the slightly cross-linked one or more rheology modifying polymers or copolymers [having the particle size described above at column 4, lines 48 to column 5, line 10], the one or more active ingredients [of no specified particle size] as well as the one or more excipients are mixed in any conventional manner to produce a blend" see column 7, lines 58-61. The particle sizes of the resulting blends are never disclosed. Thus, there is absolutely no disclosure of the particle size of the resulting agglomerate of an active ingredient and of rheology modified polymer or copolymer in Wilber et al. Of course, no tableting limitations, such as a press of no more than 2.5 tons, nor the resulting friability, hardness or capping properties of the resulting tablet are provided by the Wilber et al disclosure.

Therefore, while the Examiner believes that she was citing particle sizes of an agglomerate of a guaifenesin and binder, all that she was citing to was the particle size of the binder absent the guaifenesin. When the Patentee does describe the blending of the guaifenesin and binder, his disclosure is fatally defective as to the particle size of any resulting agglomeration of guaifenesin and binder, is silent as to the parameters upon which the tableting press operates and clearly does not specify the conditions recited in the claims and is similarly silent as to the properties of the resulting tablet.

For all the foregoing reasons, the Examiner's proposed combination of Blume et al., Dansereau et al., Troy et al., and Wilber et al., still simply fail to teach the recited steps set forth in applicants independent claim 37. The rejection under 35 U.S.C. 103 (a) absent Troy et al., also fails to establish a prima facie case of obviousness for the same reasons as discussed above.

THE DEPENDENT CLAIMS

All of the foregoing arguments have been directed only to the deficiencies of the cited references as compared to independent claim 37. It is apparent that many of the dependent claims recite limitations also not found in the proposed combination of references and not obvious in view of any independent teachings or general knowledge of one skilled in the art.

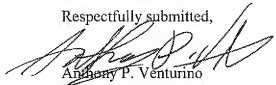
However, as each of these claims depend directly or indirectly from independent claim 37 and, by statute (35 U.S.C. 112, fourth paragraph, contain all of the limitations of the claims in which they depend, these claims are also patenable over the proposed combination of Blume et al., Dansereau et al., Troy et al., and Wilber et al., or, alternatively, Blume in view of Dansereau and Wilber et al.

Withdrawal of the rejection and passage of the application to issue is respectfully requested.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 14-1437, under Order No. 8493.017.US0000

Date: November 5, 2009

Respectfully submitted,



Anthony P. Venturino
Registration No. 31,674
NOVAK DRUCE & QUIGG LLP
1300 Eye Street, NW
1000 West Tower
Washington, DC 20005
Telephone: (202) 659-0100
Facsimile: (202) 659-0105